Humanitarian Device Exemption

Review of Humanitarian Use Devices

Nicole Wolanski, CAPT, USPHS
Premarket Approval Program
Office of Device Evaluation
Center for Devices and Radiological Health (CDRH), FDA

March 20, 2014

Overview

- Premarket Submissions
- HUDs
- HDEs
  - Criteria & Content
  - Approval
  - Key Points
  - Stats

Devices – Premarket Submissions

- Submissions for marketing clearance/approval
  - 510(k) – substantial equivalence
  - De Novo – classification of low risk devices without predicates
  - PMA – reasonable assurance of safety and effectiveness
  - HDE – reasonable assurance of safety and probable benefit

HUDs

- Humanitarian Use Device (HUD)
  - For medical devices intended to treat or diagnose a disease or condition affecting fewer than 4,000 individuals in the US per year (21 CFR 814.(n))
  - HUD designation requests are reviewed by Office of Orphan Product Development
  - Additional information - www.fda.gov/orphan

HUDs

- Nearly 7,000 rare diseases are known to affect roughly 30 million Americans.
  - approx 80% percent of rare diseases are genetic
  - about 1/2 of all rare diseases affect children
- Pediatric patients – less than 22 years of age

HDEs – Criteria & Content

- Criteria
  - Received HUD designation from OOPD and
  - Device is not otherwise available
- Content
  - Device description
  - Non clinical data: engineering, software, biocompatibility, etc.
  - Clinical experience
  - Manufacturing
  - Physician and patient labeling

HDEs - Approval

- Approval Threshold
  - Does not pose unreasonable risk of illness or injury (i.e., **safety** is demonstrated), **AND**
  - **Probable benefit** outweighs the risk (i.e., exempt from effectiveness requirements of a PMA)

- Marketing Approval
  - IRB approval required before the HUD is used (except in emergency situations)
  - Labeling must clearly identify device as a HUD, and that effectiveness for that indication has not been demonstrated

Key Points

- Requirement to show safety and ***probable benefit***
- HDE approval is marketing approval
- IRB approval required before device is used
- Annual reporting includes reassessment of qualification for HUD
- Draft guidance:
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm389154.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

HDE Stats

- 58 approved HDEs
- 8 devices approved under HDEs currently authorized to make a profit

- List of approved HDEs and their Summaries of Safety and Probable Benefit (SSPB) available at: *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm*

Contact Information

HUD Designation Information:

Office of Orphan Product Development
Eric Chen - (301) 796-6327
eric.chen@fda.hhs.gov

HDE Information:

Nicole Wolanski – 301-796-6570
nicole.wolanski@fda.hhs.gov

PMA staff – 301-796 -5640

OIR – Runa Musib – 301-796-7014